K062518

510(k) SUMMARY

DEC - 4 2006

Submitter:

Parkell, Inc.
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Farmingdale, NY 11735
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Contact:

Nelson J. Gendusa, DDS
Director of Research
Parkell
155 Schmitt Blvd.
Box 376
Farmingdale, NY 11735

Submission Date: 8 August 2006

Trade Name: Currently Not Available

Common Name: Resin Composite Restorative

Classification Name: Tooth Shade Resin Material

Equivalence: ABSOLUTE DENTIN, MARATHON DUAL-CURE COMPOSITE, PERMAFLO DC and MULTICURE COMPOSITE CEMENT

Description/Intended Use: A radiopaque, dual-cure, two-paste, resin composite restorative for use in all class cavities as the final restration. May also be used as a core material. It is supplied in 25ml, auto-mixing cartridges and employs components commonly used in predicate devices. Although biocompatibility testing was deemed to be non-essential, lab results are included as part of this submission. These indicate the material is biocompatible and non-mutagenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Nelson J. Gendusa
Director of Research
Parkell, Incorporated
300 Executive Drive
Edgewood, New York 11717

DEC - 4 2006

Re: K062518
Trade/Device Name: Celerity
Regulation Number: 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: November 22, 2006
Received: November 29, 2006

Dear Dr. Gendusa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062518

Indications for Use

510(k) Number (if known): Unknown

Device Name: SRM-DC-05-10-06
Indications for Use:

A dual-cure, tooth shade, resin composite for the restoration of Class I, II, III, IV and V cavities in permanent and deciduous teeth.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...n Sign-Off)
...ion of Anesthesiology, General Hospital,
...on Control, Dental Devices
...) Number: K062518